

REMARKS

In responding to the Office Action of September 1, 2004, Applicants conducted a telephone interview with Examiner Gabel on January 27, 2005. During this interview, the pending 35 U.S.C. §112 rejections raised by the Examiner were discussed. Applicants presented proposed amendments to claim 42 directed to methods of quantitatively or qualitatively determining an analyte using competitive assays, which was previously presented in claim 6. The Examiner indicated that these amendments will be considered and should render the present application allowable. Accordingly, by this amendment, Applicants have amended claim 42 to include that the methods utilizes a competitive assay format where labeled competitive substance competes with analyte for binding to the analyte-specific bonding partner immobilized on the solid phase. Thus, binding of the labeled competitive substance with the bonding partner brings the label in at least close proximity to the quenching substance, which is coated on the solid phase. When the sample is excited, the quenching substance allows for suppression of at least some of the signal from the labeled competitive substance and measurement from at least one phase can be taken to quantitatively or qualitatively determine the analyte.

Competitive assays employed in the claimed method that utilize a labeled competitive substance, which competes with the analyte for the analyte-specific bonding partner immobilized on the solid phase, are described in the specification at, for example, page 7, first full paragraph, page 8, second full paragraph, page 13, first full paragraph and at page 14, second paragraph to page 15, fourth paragraph. No new matter has been added.

By this amendment, Applicants have also canceled claims 2, 6, 7, 9, 45-59 without disclaimer. Accordingly, any pending rejections are rendered moot as to these claims. Applicants respectfully request entry of the amendment and allowance of the pending claims.

Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 2-7, 9-16, 19, 21, 23, 33-36, 42-45, and 47 as allegedly indefinite because the functional relationship between the analyte, labeled reagent and quenching substance is allegedly unclear. The Examiner also alleged that the phrase “the analyte determination occurs” in claim 5 is indefinite.

Applicants respectfully disagree with the Examiner’s position and submit that the claims are clear to a person of ordinary skill in the art upon reading the specification. However, solely to expedite prosecution, Applicants have amended the claims to include that the method utilizes a labeled competitive substance that competes with the analyte for binding to the analyte-specific bonding partner immobilized on the solid phase. Thus, binding of the labeled competitive substance to the bonding partner brings the label in at least close proximity to the quenching substance, which is coated on the solid phase. When the sample is excited, the quenching substance allows for suppression of at least some of the signal from the labeled competitive substance. Thus, Applicants respectfully submit that the functional relationship between the analyte, labeled competitive substance and quenching substance is clear to one of ordinary skill in the art.

With regard to the rejection of claim 5, Applicants herein amend claim 5 to include that the determination “is performed or effected” in accordance with the Examiner’s suggestion.

Applicants submit that the claims are clear to one of ordinary skill in the art. Accordingly, Applicants request reconsideration and withdrawal of the rejections based on 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 2-7, 9-16, 23, 33-36, 42-45, and 47 as allegedly lacking enablement. The Examiner asserts that the specification allegedly does not enable "the claimed method to function without physically separating unbound and bound labeled reagent." (Office Action, Page 6).

Applicants respectfully disagree with the Examiner and request that she reconsider her position. For example, in various embodiments, a known quantity of labeled competitive substance and analyte in the liquid phase are added to the assay and each competes for a limited number of bonding partners on the solid phase. As the concentration of the analyte present increases, fewer bonding positions are occupied by the labeled competitive substance and signal from unbound labeled competitive substance in the liquid phase increases and/or signal from bound labeled competitive substance immobilized on the solid phase decreases. Thus, the analyte can quantitatively or qualitatively be determined by measurement of the liquid phase and/or solid phase, without physically separating unbound and bound label. See, for example, the specification at page 7, first full paragraph and page 14, second paragraph to page 15, fourth paragraph. Accordingly, Applicants request reconsideration and withdrawal of the rejection based on 35 U.S.C. § 112, first paragraph.

Conclusion

Reconsideration and allowance are respectfully requested.

Pursuant to 37 CFR 1.136(a), an extension of time for 2 months is requested. Please charge Deposit Account No. 11-0171 in the amount of \$ 450 to cover the fee for the extension of time.

Applicants: Stemmler *et al.*
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If the Examiner has any questions regarding the present application, the Examiner is cordially invited to contact Applicants' attorney at the telephone number provided below.

Respectfully submitted,



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